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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,921	06/29/2006	Johanna Henrica Gerdina Maria Mutsaers	BHD-4662-212	1327
23117 7590 07/05/2011 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
SMITH, CHAIM A				
ART UNIT		PAPER NUMBER		
1782				
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07/05/2011		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/584,921

**Applicant(s)**

MUTSAERS ET AL.

**Examiner**

CHAIM SMITH

**Art Unit**

1782

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 May 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-9,11,12 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9,11,12 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 May 2011 has been entered.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 – 3, 5 – 9, 11, 12, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. The claimed invention is now directed to a process for the production of a food product from a whey intermediate containing annatto as a pigment wherein said intermediate containing said annatto is contacted with at least one enzyme to form a whitened whey intermediate.

5. In the disclosure applicants have broadly disclosed the bleaching of carotenoids and specifically the bleaching of Beta-Carotene. Specifically applicants' disclose the Measurement of Beta-Carotene Degradation (disclosure page 6), the degradation of Beta-Carotene (example 1), the enzymatic bleaching of a dough to which no annatto is disclosed to have been added (example 2), and the bleaching of a cheese to which no annatto is disclosed to have been added or otherwise be present. Applicant's have merely mentioned that natural colouring agents such as annatto or  $\beta$ -carotene might possibly be used as a food colouring in some cheeses, applicants' have not disclosed or provided support for the bleaching of any carotenoids other than the specific bleaching of  $\beta$ -carotene and products containing  $\beta$ -carotene. The particular cheeses disclosed by the applicants where the whiteness of the cheese might be a problem are cheeses made at least partially with cow's milk in which  $\beta$ -carotene would be present. Applicants have not set forth or cited any examples of any enzymatic bleaching with respect annatto or annatto containing products in the disclosure.
6. Similarly with respect to the use of a whey intermediate. Applicants disclose that the intermediate form of a bread product would contain water, salt, yeast, the mixed dough, and partially baked dough. There is no mention of the use of whey or that said whey would possibly contain annatto as a pigment. Applicants' disclose the intermediate form of a noodle product would contain water, salt, other noodle ingredients, the mixed dough, and the final product. There is no mention of the use of whey or that said whey would possibly contain annatto as a pigment. For a soft cheese the intermediate products are milk and cheese curd. While applicants' disclose the

preparation of a cheese product, the whey is not seen to be an intermediate since the whey is separated as a by product of the cheese making process and not an ingredient added to the cheese making process. It is also noted that applicants' do not even require the use a bleaching enzyme in the preparation of a cheese product ("in case the experiment involved the use of bleaching enzyme", i.e. if an enzyme were to be used at all) (page 9 paragraph 2). Further the use of annatto is not disclosed as an added ingredient to any product, intermediate or otherwise. Thus the applicants have not set forth any examples of the use of whey as an intermediate or that said whey would even contain annatto.

7. The specification fails to provide any representative examples of the claimed species to show that applicant was in possession of the claimed species. A representative number of species means the species which were adequately described and representative of the entire genus. The written description requirement for a claimed species may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed species which the applicants have not done. Therefore the limitation of "contacting a whey intermediate" specifically "containing annatto as a pigment" is seen to constitute an issue of new matter (see MPEP § 2163.05 II.).

8. Claims 2, 3, 5 - 9, 11, and 12 are rejected by virtue of their dependence on a rejected base claim.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1 - 3, 5 - 9, 11, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brody et al. US 6,120,820 in view of Zorn, Applied Microbiology and Biotechnology 62:331 - 336, 2003 further in view of US Dairy Export Council, Davisco Foods International, and FASonline.

12. Regarding claims 1 – 3 and 15, Brody discloses a process for the production of a food product (reduced color whey product) (col. 11, paragraph 4) which comprises contacting a whey intermediate containing annatto as a pigment with at least one bleaching agent for which annatto is a substrate under conditions such that at least a portion of the annatto present in the whey intermediate is converted to a form a

whitened whey intermediate. Brody further discloses that any suitable bleaching material would be used (col. 11, paragraph 2).

13. Claim 1 differs from Brody in specifying the use of an enzyme which is a direct conversion enzyme. Zorn discloses the bleaching of carotenoids,  $\beta$ -carotene, (degradation) can be accomplished by the use of fungal enzymes. In order to determine which fungal source enzymes would provide optimal bleaching activity (degradation) in carotenoids such as  $\beta$ -carotene. Zorn measured said activity by a conventional photometric bleaching test in which the enzymatic activities were measured by the amount of bleaching (degradation) occurring in  $\beta$ -carotene. Zorn therefore discloses that is, it is conventional and known in the art that carotenoids are bleached by fungal based enzymes. *M. scorodoni* in particular was characterized by Zorn as having a high activity with respect to the degradation of  $\beta$ -carotene (Zorn; abstract, page 333, col. 2, paragraph 3, table 1 and page 334, col. 1, bottom of the page, table 2). While Zorn is cleaving  $\beta$ -carotene, a carotenoid, to derive flavor compounds Zorn discloses that it is known in the art that the bleaching of carotenoids can be accomplished using fungal based enzymes, which is also applicant's intended reason for the use of such enzymes. Once it was known that a particular enzyme would bleach carotenoids the substitution of one conventional method known to bleach carotenoids for another conventional method, such as the enzyme shown by Zorn to bleach carotenoids is seen to have been an obvious matter of choice and/or an obvious result effective variable, particularly if higher activities were known to be present in one variety over another as is seen in table 2 of Zorn. To therefore modify Brody and use a

direct converting enzyme to bleach a food product would have been an obvious matter of choice and/or an obvious result effective variable. An express suggestion to substitute one equivalent component for another is not necessary to render such substitution obvious (MPEP 2144.06 II.). Further given that it was well established that  $\beta$ - carotene would be bleached by fungal based enzymes, in particular *M. scorodoni*, and that  $\beta$ - carotene and the active coloring compound of annatto are both carotenoids it would have been obvious to try to bleach an annatto containing intermediate based on the teachings of Zorn, that is, to choose from a finite number if identified, predictable solutions, with a reasonable expectation of success.

14. Further, Brody is preparing a food product from the whitened whey intermediate obtaining in step (a) (spray dried product) Further as evidenced by US Dairy Export Council, Davisco Foods International, and FASonline, it was conventional and well established to use whey intermediates to prepare flour and/or dairy based food products. To therefore have used the whey intermediate or Brody in view of Zorn to prepare a flour based or a dairy based food product would have been an obvious matter of choice and/or an obvious result effective variable.

15. Regarding claims 5, 6, 7, and 12 Brody in view of Zorn further in view of US Dairy Export Council, Davisco Foods International, and FASonline discloses the enzyme is added as an enzyme preparation derived from a microorganism or produced in situ by a microorganism, that is, in particular, *Marasmius scorodoni* (Zorn; abstract) which is a fungus (Zorn; page 331, paragraph 3),.



16. Regarding claims 8 and 9, since Brody in view of Zorn further in view of US Dairy Export Council, Davisco Foods International, and FASonline discloses a method of making a food product by the process according to claim 1 (bread) ('336; title) it is expected that the product would have been made by the process a claimed. Further Brody in view of Zorn further in view of US Dairy Export Council, Davisco Foods International, and FASonline discloses that the at least one part of the food product has been subjected to treatment with an enzyme according to the process of claim 1 (whey product).

17. Regarding claim 11, absent evidence of criticality it is not seen that patentability would be predicated on the use of wheat flour since it is notoriously old and established to provide food products prepared from wheat flour. In any case Brody in view of Zorn further in view of US Dairy Export Council, Davisco Foods International, and FASonline disclose the use of wheat flour to prepare food products was conventional (US Dairy Export Council, page 4, col. 2).

### ***Response to Arguments***

18. Applicant's arguments with respect to claims 1 – 3, 5 – 9, 11, and 12 have been considered but are moot in view of the new ground(s) of rejection.

19. Further applicants' are referred to MPEP § 2112. I. The discovery of a previously unappreciated property of the prior art enzyme, *Marasmius scorodoni* in this case, that is, the bleaching (cleavage) of carotenoids other than  $\beta$ - carotene by the enzyme does not render the enzymes property patentably new. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not make

the claim patentable. Zorn discloses that the co-oxidation, that is bleaching, of carotenoids have been intensely investigated. Given that Zorn is disclosing the enzymatic bleaching of related carotenoids it would have obvious to one of ordinary skill in the art to apply the known work of Zorn to other carotenoid compounds. Choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success in view of Zorn would have been obvious.

### ***Conclusion***

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHAIM SMITH whose telephone number is (571)270-7369. The examiner can normally be reached on Monday-Thursday 7:30-5:00.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1782  
25 June 2011

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